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CONTRACTING ORGANIZATION: The Geneva Foundation
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13. ABSTRACT (Maximum 200 Words)

The purpose of this study is to examine a population-based intervention using preventive measures of a remote call-based asthma disease management program utilizing proactive education and monitoring. This intervention will be compared to a control population of pediatric asthma patients receiving printed education materials and usual care at three DoD military treatment facilities in a similar geographic region. Comparison will be made to examine differences in patient and caregiver quality of life (QOL), disease severity (as measured by reduced inhaled short acting beta agonist use), pulmonary function as measured by peak flow and spirometry (FEV1), and Emergency Department visits and hospital admissions.

To date the study has obtained IRB approval, established and utilized the contracting organization to hire study staff and reimburse the selected disease management (DM) firm. Needed supplies and equipment were purchased. A research database was created. Rollout procedures visits to the sites and DM firm were completed as were subsequent quality assurance visits. The study population was identified, recruited and enrollment was completed with 451 patients. Patients have been randomized and the DM firm is performing call-based disease management. Seventy-one patients have completed the study. The remaining patients will be completing the trial through Dec 2004.

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Introduction

Background: Call-center based disease management programs (CBDMP) are used in the commercial healthcare industry, however, they have not been utilized in the Military Health System (MHS). They provide population based proactive education and monitoring for specific disease states. Patients are educated and empowered to seek treatment according to nationally accepted guidelines for their particular condition. Asthma is the number one reason for childhood hospitalizations in the MHS, has a significant impact on missed school days, and impacts duty restrictions for asthmatic child caregivers. This study will conduct a benefit analysis of an alternative disease management (DM) process.

Objective/Hypothesis: That a CBDMP, applied to asthma, will:

- Improve patient and caregiver quality of life (QOL)
- Reduce disease severity, as measured by reduced inhaled short acting beta agonist use
- Improve patient condition as measured by Peak Expiratory Flow
- Reduce Emergency Department (ED) visits and hospital admissions

Specific Aims: This study will measure the impact of CBDMP, which promotes patient education and empowerment, on multiple factors to include; patient/caregiver quality of life, patient peak flow values, and utilization of MHS and MCSC healthcare resources. The study will assess the impact on an asthmatic population randomly selected from three military TRICARE Prime communities, to see if CBDMP improves patient health compared to a control group selected from the same three communities. It will also quantify cost savings/avoidance as a result of such programs.

Body

The original approved Statement of Work appears in black. Text in *italics* describes the accomplishments associated with each task.

Statement of Work

All dates are from the time of grant acceptance. Assuming grant funds are not delayed.

Months 1-3: IRB review and approval, coordinate with Geneva Foundation for establishment of trust fund and trust fund disbursements processes. (Geneva has already agreed to be the trust agent). Purchase PC for study coordinator, prepare statement of work for DM firm bids.

IRB approval has been obtained. The Geneva Foundation established the trust and has been disbursing funds as requested. The study coordinators all have computers. The statement of work for the Disease Management (DM) firm was completed

Month 3: Geneva to hire program administrator, offer DM statement of work for DM for bid, identify asthmatics in three study locations. Purchase peak flow meters. Prepare and reproduce patient education materials, and informed consent work sheets. Contract Oracle data base administrator to establish database for research data collection. Contract peak flow meter data collection web site support.

The program administrator and site coordinators have been hired. The DM statement of work was put out for bid. Asthmatics in the three study locations have been identified. Electronic peak flow meters have been purchased. Patient education materials and informed consent documents have been reproduced. A web-based Oracle data-base was determined to be both prohibitively expensive and in peril of violating at the time existing standards of privacy and systems security within the DoD computer systems and would with near certainty violate the evolving HIPPA and DoD systems security as identified at the time. An in-house security/privacy compliant Microsoft Access Database was created for research data collection. The company utilizing web based site support for peak flow meters went out of business. The peak flow company contracted is able to support electronic data transmission but not web based support.

Months 2 – 4: Receive bids, select DM firm. Geneva to arrange for 1 additional study assistant to help with initiation of study, material distribution, and study participant recruitment and education. Coordinate data exchanges with DM firm and research group. Potential study population identified from available military and Foundation Health

databases. Establish research database at Tricare Southwest. Travel to DM firm to make arrangement for rollout and data integration. Travel to study location to educate providers about the program that their patients may be randomly selected to enter.

Bids were received and a DM firm was selected – National Jewish Medical and Research Center. The Geneva Foundation hired a coordinator at each site after approval and additional funding from PRMRP. Data exchange was coordinated with the DM firm. The potential study population has been identified via military and Foundation Health databases. Tricare Southwest has established a research database. Travel to the DM firm, arrangement for rollout and data integration was accomplished. Travel to the study sites with rollout education was accomplished.

Months 1 - 12: PI visit to Texoma for brief provider education. Contact study participants, describe study and consent documents. Collect informed consents. Basic educational material and spirometer to all study participants. Collect baseline information and QOL. Randomized subjects to control or intervention group. Begin CBDMP support

Principle Investigator (PI) visit to Texoma for provider education and rollout was accomplished. Study participants have been contacted and enrolled. Informed consents have been signed and collected. Enrollment began in January 2003 and closed in December 2003 with 451 total patients enrolled. Educational materials have been given to all participants. In order comply with national guidelines; the protocol was amended with IRB approval to distribute peak flow meters only to patients with persistent asthma (mild persistent, moderate persistent, severe persistent) and to defer peak flow distribution to mild intermittent asthmatics unless requested by any patient's healthcare provider. Anticipated savings and an IRB approved amendment allowed the purchase of a spirometer for each site to measure FEV1. Baseline QOL information has been obtained. Patients have been randomized and the DM firm has been implimenting call-based disease management.

Months 1 – 24: Collect retrospective MCSC claims, CHCS encounter and medication on all study participants in both the intervention and control groups as they enter and continue with the program. DM intervention and prospective data collection begins. Data collection/enrollment will be for 12 consecutive months. Data transferred from DM firm and entered into research database. Research assistants to contact control groups and collect data every 6 months (QOL). Conduct patient satisfaction surveys for the intervention group when they

complete the study. Make quality assurance visit to DM firm and study office in Texoma

To standardize the process of analysis and improve efficiency, claims, pharmacy, and provider visit analysis will be done at completion of the study for individual patients looking back two years (with separation of year one vs year two) rather than analysis at enrollment looking back one year and at completion looking back one year. Our study staff at the TRICARE lead agent are engaged with the medical informatics staff to begin accumulating that data on patients as they close-out in the study. DM intervention and data collection continues. Patients are being followed at the 6 month point to collect QOL, peak flow, medication, missed school/work, admission/emergency department visits, and spirometric data. Interim quality assurance visits to DM firm (once in June 2003) and to sites in Texoma (once in June 2003 and once in October 2003) have been accomplished.

Months 15-27: Collection of last 12 months of healthcare resource utilization, QOL and PEF data (must wait 3 months post intervention for reliable claims data to be recorded)

As above, the look at closeout regarding healthcare utilization will be for two years retrospective with separation on year one (pre-enrollment) vs year two (intervention). Our study staff at the TRICARE lead agent are engaged with the medical informatics staff to begin accumulating that data on patients as they close-out in the study. QOL, PEF, and spirometry are being collected and 71 patients have completed the study through 31 March 2004.

Months 28-29: Final data analysis

The study is still in progress.

Months 29-30: Findings and conclusion write up.

The study is still in progress.

Key Resesarch Accomplishments

From first annual review:

- IRB approval obtained at both Wilford Hall Medical Center and Brooke Army Medical Center
- The Geneva Foundation established as contracting organization
- Study staff hired at each of the three sites
- Bids received and DM firm selected – National Jewish Medical and Research Center
- Study population identified via military and Foundation Health databases
- Electronic peak flow meters purchased
- Patient education materials and informed consent documents reproduced
- Research database established by Tricare Southwest
- Traveled to the DM firm to review and establish rollout procedures
- Traveled to three sites to review rollout and provide education/overview to primary care providers
- Study participants contacted and enrolled beginning January 2003 - 115 patients to date
- Patients randomized and DM firm performing call-based disease management

New for this second annual review

- Study participants contacted and enrolled with enrollment closed in December 2003 after enrolling 451 patients
- Retention to date has been excellent with only 5 patients withdrawn and 7 lost to follow-up
- Seventy one participants have completed the study
- Electronic database has been modified and updated to capture all outcomes data for 6 month and 1 year/closeout visits
- Quality assurance visits have been undertaken to the DM firm (one to date) and to the sites (two to date)
- TRICARE lead agent has provided pharmacy data for participants that have completed the study and data is being entered
- TRICARE is engaged with the medical informatics staff to accumulate utilization and cost data on patients and to manipulate the format for most efficient analysis

Reportable Outcomes

Enrollment Data

Site	Number intervention group/Number enrolled	Number completed[2]	Number withdrawn[2]	Number lost to follow-up[2]
Tinker AFB	71/142	30	0	2
Ft Sill	77/154	15	3	2
Sheppard AFB	77/155	26	2	3
Totals	**225/451**	**71**	**5**	**7**

Site	Mild Intermittent (%)	Mild Persistent (%)	Moderate Persistent (%)	Severe Persistent (%)	Mean Age (yr)	Male (%)	Mean FEV1 (L)	Mean FEV1 (% Predicted)
Tinker AFB	32	60	8	3	12.53	68	2.32	101
Ft Sill	27	39	29	5	13.45	62	2.02	94.3
Sheppard AFB	26	32	38	4	11.58	53	2.01	94.5
Totals	28	43	25	4	12.52	59	2.11	96.4

Conclusions

None

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Appendices

Appendix 1 Informed Consent (Attached)

FWH20020030H

BROOKE ARMY MEDICAL CENTER/WILFORD HALL MEDICAL CENTER
INFORMED CONSENT DOCUMENT
(ICD Template Version 4. Feb 02)

CALL CENTER-BASED DISEASE MANAGEMENT (CBDMP) OF PEDIATRIC ASTHMATICS

This consent document is written in second person for those individuals completing it for their own participation in the study. The language should be considered to refer to the research subject when a parent/guardian or legal representative is completing the form on the research subject's behalf (example: a child). Therefore, this informed consent document will serve for adult, child or surrogate/substitute consent.

PRINCIPAL INVESTIGATOR – Dr James M Quinn, Lt Col, USAF, MC

If you choose not to participate in this research study, your decision will not affect your eligibility for care or any other benefits to which you are entitled.

DESCRIPTION/PURPOSE OF RESEARCH
You are being asked to consider participation in this research study. The purpose of this study is to evaluate the impact of a telephone education program on patient understanding of asthma and their ability to manage the condition. The impact will be measured in a number of ways to include monitoring the number of emergency room visits, hospitalizations, and other medical care resources. It will also monitor quality of life and lost days of school/work for study subjects and their health caregiver (i.e. mother, father, etc).

AND

This study will enroll a total of 600 subjects overall, with approximately 200 subjects from each of the locations (Sheppard AFB and Tinker AFB). Patients will be enrolled over a period of 12 months.

AND

During your participation in this study, you will continue to see your usual health care provider for regular health visits at the interval that he/she feels necessary for your care. Over the 12 month period of the study, you will be asked to make approximately 2 outpatient visits with the study coordinator or the associate investigator at your location.

AND
You have been selected to participate in this study because you have been identified as having asthma..

PROCEDURES:

As a participant, you will undergo the following procedures:

There will be two groups – an "intervention" group and a "comparison" group. The "intervention" group will be periodically contacted by an asthma management organization consisting of specialty trained nurse educators. They will provide asthmatics educational support for the management of their condition. During these periodic calls, the intervention group will be assessed for their understanding of their disease and their ability to manage it. Should the asthma nurse believe additional education is needed it will be offered. The frequency of the calls will be determined by the severity of the condition. Call frequency may be as often as every 2 weeks. All calls will be scheduled in agreement with you and the asthma management organization.

The "comparison group will also be contacted every 1-3 months, by phone or mail, for an assessment of their asthma and for peak flow values. However, there will be no additional education during the course of the study.

Patients in both groups will initially be asked a series of questions regarding signs and symptoms of their asthma and to answer quality of life questions, to include use of medical resources (hospitals, emergency rooms, and other health care resources). Initially, a breathing or pulmonary function test will be performed. The test involves breathing forcefully into a tube connected to a computer. Additionally, patients in both groups with persistent asthma will be given or mailed a peak expiratory flow ("Peak Flow") meter, which can be connected to a computer. The values may be transmitted electronically via computer or the meter may be brought or mailed to the study coordinator at the local Military Treatment Facility. Both groups will be periodically contacted at no less than 6 month intervals to return to the study coordinator or local associate investigator to answer quality of life questions, to include use of medical resources (hospitals, emergency rooms, and other health care resources) and to repeat breathing/pulmonary function testing. Should the study subject be a minor, the guardian will be asked about lost time from work as a result of the patient's illness.

AND

For Protocol Office Use Only:
FWH20020030H, Quinn, ICD, 23 Sep 03

WHMC INSTITUTIONAL REVIEW BOARD

23 Sep 03
Date ICD Approved by IRB

22 Sep 04
Date ICD Expires

As a participant, you will be randomly assigned to one of two treatment plans. Randomization is a process like flipping a coin and means you will have a chance of being assigned to any of the plans.

You will be randomly assigned to one of two groups. The first group, or "intervention" group will receive additional asthma education on the phone from an asthma management organization. The second group is the "comparison" group. This group will receive a one-time asthma educational pamphlet from a reputable source through the mail or from study personnel.

AND
If you need a procedure requiring additional informed consent, a separate consent form will be given to you before that procedure.

RISKS OR DISCOMFORTS:
There is no known risk associated with this study.

BENEFITS:
The possible benefit of your participation in this study is increased understanding of asthma, and how to monitor and treat it.

This study is intended to benefit you. At this time, it is not known if the most commonly accepted treatments achieve the best possible results. The investigators have designed this study to learn if the new treatment is as good as or better than or worse than the most commonly accepted treatments.

There is no guarantee you will receive any benefit from this study other than knowing that the information may help future patients.

PAYMENT (COMPENSATION)
You will not receive any compensation (payment) for participating in this study.

ALTERNATIVES TO PARTICIPATION:
Alternatives may be available to you. These may include other treatments.
OR
Supportive care to reduce symptoms rather than treat underlying causes may be the only alternative treatment available for you.
AND
Choosing not to participate in this study is your alternative to volunteering for the study.

WHMC INSTITUTIONAL REVIEW BOARD

23 Sep 03
Date ICD Approved by IRB

22 Sep 04
Date ICD Expires

CONFIDENTIALITY OF RECORDS OF STUDY PARTICIPATION:
Records of your participation in this study may only be disclosed in accordance with federal law, including the Federal Privacy Act, 5 U.S.C. 552a, and its implementing regulations. DD Form 2005, Privacy Act Statement- Military Health Records, contains the Privacy Act Statement for the records.

By signing this consent document, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further medical science. You will not be personally identified; all information will be presented as anonymous data.

Your records may be reviewed by the U.S. Food & Drug Administration (FDA), other government agencies, the BAMC/WHMC Institutional Review Boards, and by the United States Army Research and Material Command.

Complete confidentiality cannot be promised, particularly for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities.

ENTITLEMENT TO CARE:
In the event of injury resulting from this study, the extent of medical care provided is limited and will be within the scope authorized for Department of Defense (DoD) health care beneficiaries.

Your entitlement to medical and dental care and/or compensation in the event of injury is governed by federal laws and regulations, and if you have questions about your rights as a research subject or if you believe you have received a research-related injury, you may contact the

Wilford Hall Clinical Research Squadron Commander, (210) 292-7069, Wilford Hall Medical Center Risk Manager, 210-292-6004, or the Wilford Hall Medical Center Judge Advocate General, 210-292-7808

AND
Brooke Army Medical Center Protocol Coordinators, 210-916-2598 or BAMC Judge Advocate, 210-916-2031.

BLOOD & TISSUE SAMPLES:
No blood or tissue samples will be collected as part of this study

For Protocol Office Use Only:
FWH20020030H, Quinn, ICD, 23 Sep 03

WHMC INSTITUTIONAL REVIEW BOARD

23 Sep 03
Date ICD Approved by IRB

22 Sep 04
Date ICD Expires

VOLUNTARY PARTICIPATION:

The decision to participate in this study is completely voluntary on your part. No one has coerced or intimidated you into participating in this project. You are participating because you want to. The Principal Investigator or one of his/her associates has adequately answered any and all questions you have about this study, your participation, and the procedures involved. If significant new findings develop during the course of this study that may relate to your decision to continue participation, you will be informed.

You may withdraw this consent at any time and discontinue further participation in this study without affecting your eligibility for care or any other benefits to which you are entitled. Should you choose to withdraw, you must notify the Principal Investigator, your local Associate Investigator, or a Study Coordinator of your intent to withdraw. If you are reassigned during the period of study you may be able to continue some participation at your new duty assignment though telephone, or mail contact. If you do not follow these procedures, you are unlikely to suffer significant health affects but may increase the risk that you will have less of an understanding and/or ability to self manage your asthma without contacting your provider. Your condition will continue to be treated in accordance with acceptable standards of medical treatment.

The investigator of this study may terminate your participation in this study at any time if he/she feels this to be in your best interest.

CONTACT INFORMATION:

Principal Investigator (PI)

The principal investigator, Lt Col. James Quinn, or a member of the research team will be available to answer any questions concerning procedures throughout this study at (210) 292-5717, DSN 554-5717.

For patients at locations other than Wilford Hall, additional local points of contact include the local Associate Investigators listed as follows:

Tinker AFB: Dr Eric Dedeke, Family Medicine, (405) 736-4765, DSN 336-4765
Sheppard AFB: Dr Andrew Lapadat, Pediatrics, (940) 676-6777, DSN 736-6777

Principal Investigator: Dr James M. Quinn, Lt Col Phone: (210) 292-5717

Institutional Review Board (IRB)

The WHMC Institutional Review Board (IRB), the hospital committee responsible for safeguarding your

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rights as a research subject, has assigned a member of the IRB, who is not part of the study team, to serve as an outside monitor for this study (this person is the Medical Monitor). If you have any questions about your rights as a research subject or any other concerns that cannot be addressed by the PI, you can contact the medical monitor, Joseph Schmelz, PhD, RN at (210) 292-5687. Or mail to: 59th Clinical Research Squadron/MSRP, 1255 Wilford Hall Loop, Lackland Air Force Base, Texas 78236.

In addition, if you have any comments, questions, concerns or complaints, you may also contact the Chairperson of the IRB, at (210) 292-7558. Or mail to: 59th Medical Wing/CM, 2200 Bergquist Drive, Lackland Air Force Base, Texas 78236.

Your consent to participate in this study is given on a voluntary basis. All oral and written information and discussions about this study have been in English, a language in which you are fluent.

A copy of this form has been given to you.

VOLUNTEER'S SIGNATURE **VOLUNTEER'S SSN** **DATE**

VOLUNTEER'S PRINTED NAME **FMP** **SPONSOR'S SSN** **DOB**

VOLUNTEER'S ADDRESS (street, city, state, zip)

ADVISING INVESTIGATOR'S SIGNATURE **DATE** **(PHONE NUMBER)**

PRINTED NAME OF ADVISING INVESTIGATOR

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WITNESS' SIGNATURE **DATE**
(Must witness ALL signatures)

PRINTED NAME OF WITNESS

(If the subject is a minor and in the opinion of the attending provider, the minor can understand the nature and consequences of participation in the study, the minor should sign above. If the minor is determined to be able to understand but is unable to sign, the advising investigator will indicate the minor has orally assented to participate in the study by placing the investigator's initials here: _____)

PARENT'S OR GUARDIAN'S NAME (Typed or Printed)

PARENT'S OR GUARDIAN'S SIGNATURE **DATE**

PARENT'S OR GUARDIAN'S NAME (Typed or Printed)

PARENT'S OR GUARDIAN'S SIGNATURE **DATE**
(Generally, both parents or guardians should sign the consent, if a minor is involved.)

(If the legal representative has a copy of the power of attorney or court appointment, attach it to this consent document and sign below:)

LEGAL REPRESENTATIVE'S NAME (Typed or Printed)

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LEGAL REPRESENTATIVE'S SIGNATURE **DATE**

Subject's Stamp Plate
PRIVACY ACT OF 1974 APPLIES.
DD FORM 2005 FILED IN MILITARY HEALTH RECORDS

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